



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

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February 23, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re Docket No. 99N-2497
Citizen Petitions: Actions That Can be Requested by Petition; Denials,
Withdrawals, and Referrals for Other Administrative Action
64 FR No.229. 66822-66828 (November 30, 1999)

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the proposed rule "Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action". These comments are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 850 member companies of these associations operate more than 1550 processing and manufacturing plants, which account for 85% of dairy products consumed in the United States.

We agree with the need to improve and make FDA's citizen petitions process more efficient and more responsive. However, we oppose the change proposed by FDA, specifically the limitations of actions that may be requested by a citizen petition. We agree that citizen petitions pertaining to significant public health issues should certainly receive priority of resources. However, we are deeply concerned that changes proposed in section B of this rule, §10.30(e)(2)(ii) – *Denial of Citizen Petitions*, would not allow FDA to fully review and consider many important petitions pertaining to issues other than public health. It is imperative that FDA not deny a petitioner's request relating to Standards of Identity and food labeling regulations. Petitions which involve economic issues or agency procedures such as food labeling and standards fall within the Agency's statutory jurisdiction and should be fully considered and acted upon as allowed by the

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current policy. We do not agree that the Agency should limit the denial of a citizen petition, of non public health issues but nevertheless important, with a "brief" response.

The International Dairy Foods Association disagrees with the changes proposed in part A of the proposed rule, § 10.30(b) – *Actions That May Be Requested in a Citizen Petition*. This proposed change would not allow citizen petitions that address other administrative actions. These changes would exclude many important petitions such as petitions filed to issue or amend guidance documents, petitions relating to Agency decisions, or petitions to reopen administrative records in pending rule making.

In efforts to improve speed and efficiency of citizen petitions it was proposed that an informal method of communication with the Agency be undertaken with regards to effecting a pending order or issuing an order. In this case it is proposed that a person who desires to present information to FDA do so through letter, electronic mail, meeting or discussion. Even though informal communication with the Agency is effective on many issues, we disagree agree with this approach as a substitute to citizen petitions. Informal correspondence is not an adequate way to raise an issue normally covered in citizen petitions. Currently the lack of proper FDA resources has created a backlog in responding to formal petitions; often FDA is unable to fully respond in the required 180 day timeframe. There is no evidence that informal correspondence will be reviewed and considered by high level FDA officials. There is also no requirement for the Agency to reply to informal communications in a specific time frame or even reply at all. Additionally, Agency responses to informal correspondence may not be subject to judicial review. The proposed rule stated that the back log of petitions is due to many inconsequential submissions, however there is nothing in the current regulations that requires a great deal of time be expended to petitions which are easily identified as frivolous or outside the jurisdiction of FDA.

We urge the Agency to continue with the current citizen petition policy. The goal of the citizen petitions is to allow all stakeholders, industry, trade associations and consumers, to have input in government. This proposal would take the inner workings of the FDA further away from the people and reduce transparency in government. Moving important policy decisions from public to private correspondence is contradictory to the spirit of the Federal Food and Drug Modernization Act (FDAMA)

If the Agency does undertake changes to the citizen petition, IDFA agrees with specific sections proposed for denials of citizen petitions. We agree that if a petitioner makes a request outside of FDA's legal authority, a brief response would be warranted. We also support the proposed sections § 10.30(e)(4)(ii) and (iii), addressing clarification of petitions and withdrawal in specific cases. The Agency should have the authority to seek clarification of a petitioner's request. We also concur that FDA should be able to consider a petition withdrawn where the Agency has confirmed that the petitioner no longer exists or the petitioner clearly states that it does not seek a response.

IDFA appreciates the opportunity to comment on the proposed changes to the process of submitting citizen petitions and would welcome the opportunity to discuss these issues. We are also glad to answer questions or provide additional information.

Respectfully submitted,

A handwritten signature in black ink that reads "Cary Frye". The signature is written in a cursive, flowing style.

Cary Frye
Vice President, Regulatory Affairs